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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/688,539
Filing Date: October 17, 2003
Appellant(s): ECHOLS ET AL.

Patrick R. Scanlon
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10-20-08 appealing from the Office action mailed 1-22-08.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The Examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The amendment after final rejection filed on 6-5-08 has not been entered.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The Appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,132,751	SUZUKI	10-2000
5,540,930	GUY	07-1996
4,883,658	HOLLY	11-1989

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Rejection 1:

Claims 1-6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The distinction between the hydrophilic polymer and the polyvinyl acetate and polyvinyl alcohol in claim 1 is unclear. Both the acetate and the alcohol are considered hydrophilic polymers so it is unclear if an additional component is needed to meet the limitation of "hydrophilic polymer" in the claimed compositions.

Rejection 2:

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki (6,132,751) in combination with Guy (5,540,930) and Holly (4,883,658).

Suzuki discloses emulsion compositions for eyes drops. The compositions contain water, phospholipids such as lecithin, polyvinyl alcohol, a hydrophilic polymer polyvinyl pyrrolidone, and additionally contain isotonizing agents such as glycerol and solvents such

as ethanol (col. 4, line 17-26, col. 6, lines 54-67, col. 7, lines 33-44, Examples). Suzuki does not teach inclusion of polyvinyl acetate in their composition. Moreover, Suzuki does not teach the inclusion of polysorbate-80 (Tween 80) in their composition.

Guy discloses eye formulations. The formulations contain water, polyvinyl pyrrolidone (PVP), polyvinyl alcohol (PVA), glycerol and Tween 80 (col. 2, lines 4-5, col. 3, line 10 through col. 4, line 19).

Holly, while disclosing ophthalmic solutions for treatment of dry-eye syndrome, teaches that the combination of an aqueous solution of a partially hydrolyzed polyvinyl acetate and polyvinyl alcohol is synergistic. The compositions further contain polyvinylpyrrolidone (abstract, col. 3, line 51 through col. 5, line 27, examples and claims).

The addition of polyvinyl acetate in Suzuki would have been obvious to one of ordinary skill in the art at the time of the invention since the combination of polyvinyl acetate and polyvinyl alcohol is beneficially synergistic as taught by Holly.

To include a surfactant such as Tween 80 in the formulations of Suzuki would have been obvious to one of ordinary skill in the art at the time of the invention since Guy, who teaches ophthalmic formulations, teaches the use of a non-ionic surfactant such as Tween 80.

Rejection 3:

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki (6,132,751) in combination with Guy (5,540,930) and Holly (4,883,658) as set forth above, further in view of applicant's statements of prior art.

The teachings of Suzuki, Guy and Holly have been discussed above. Suzuki in particular teaches the use of lecithin, glycerol, ethanol and water.

On page 6 of the specification, Appellants state that the combination of lecithin, ethanol, glycerol, polysorbate 80 is readily available on the market under the trade name Amisol™. One of ordinary skill in the art would be motivated to use Amisol™ since it already contains premixed lecithin, ethanol, glycerol and polysorbate 80, the individual components taught by Suzuki and Guy in particular.

(10) Response to Argument

Rejection 1:

Appellant's arguments have been fully considered but are not persuasive. The issue here is the distinction between the generic hydrophilic polymer and the specific polymers, polyvinyl alcohol and polyvinyl acetate, recited. The claims do not recite polyvinyl acetate, polyvinyl alcohol and a hydrophilic polymer other than these two. Appellant argues that one of ordinary skill in the art when reading claim 1 in light of the specification would understand that the recitation of hydrophilic polymer in claim 1 would mean a hydrophilic polymer other than polyvinyl acetate and polyvinyl alcohol. This argument is not persuasive since the specification does not define this term in terms of specific compounds.

Rejection 2:

Appellant's arguments have been fully considered, but are not persuasive. Appellant agues the following: "Suzuki discloses an emulsion composition, the primary components of which are: 1) one drug selected from the group consisting of fluorometholone, clobetasone butyrate and clobetasol propionate, 2) a phospholipid, 3) liquid paraffin, and 4) water (see column 2, lines 5-14). In the last paragraph of column

6, Suzuki et al mentions other non-essential components that can be included in the emulsion. These additional components include thickeners such as polyvinyl pyrrolidone and polyvinyl alcohol, among others. Examples 16 and 23 describe using polyvinyl alcohol but not polyvinyl pyrrolidone. Examples 17 and 24 describe using polyvinyl pyrrolidone but not polyvinyl alcohol. Suzuki et al does not disclose using both polyvinyl pyrrolidone and polyvinyl alcohol together in the same composition. Thus, Suzuki et al describes a composition including a phospholipid and a hydrophilic polymer (i.e., polyvinyl pyrrolidone) and a composition including a phospholipid and polyvinyl alcohol, but Suzuki et al does not disclose a composition that includes the three components of a phospholipid, a hydrophilic polymer (polyvinyl pyrrolidone), and polyvinyl alcohol. The Examiner has not provided any reason as to why it would have been obvious to one of ordinary skill in the art to provide the composition of Suzuki et al with both polyvinyl alcohol and a hydrophilic polymer such as polyvinyl pyrrolidone with a phospholipid".

These arguments are not persuasive. Instant claims do not exclude an emulsion. In fact, instant claims recite the same lipophilic lecithin and water and therefore, an emulsion is not excluded. With regard to Appellant's arguments that Suzuki does not teach polyvinyl alcohol and polyvinyl pyrrolidone together, the Examiner points out that Suzuki on col. 6, line 64 teaches that these are thickeners and it is within the skill of the art to combine two thickeners to achieve a desirable thickness with the phospholipid of Suzuki. Furthermore, the combination of all three polymers is taught by Holly.

Appellant argues that another difference between Suzuki and claim 1 is that Suzuki does not disclose polyvinyl acetate and that the Examiner contends that the addition of polyvinyl acetate in Suzuki would have been obvious since the combination of polyvinyl acetate and polyvinyl alcohol is synergistic as taught by Holly. While acknowledging that Holly does describe mixing polyvinyl acetate and polyvinyl alcohol to be synergistic, Appellant argues that just because a mixture of two elements is taught to be synergistic does not mean it would be obvious to combine these two elements in every composition that contain one of the two elements. According to Appellant, Suzuki is concerned with increasing the solubility of drugs such as fluorometholone, clobetasone butyrate and colbestasol propionate so as to facilitate dispensing these drugs via aqueous eye drops; and Suzuki is not concerned with tear film instability, which is the problem that the Holly patent is concerned with. Further according to Appellant, there is no suggestion that lowering surface tension by adding polyvinyl acetate to the polyvinyl alcohol already present in the Suzuki et al composition will improve the ability to dispense drugs such as fluorometholone, clobetasone butyrate and clobetasol propionate. Accordingly, one of ordinary skill in the art would not have been taught by Holly to add polyvinyl acetate to the compositions of Suzuki et al or Suzuki et al combined with Guy et al. This argument is not persuasive. First all of all, three references are concerned with ophthalmic compositions. Holly clearly states that the composition is effective as an aqueous vehicle for topically used ophthalmic drugs or nutrients (abstract). Secondly, on col. 1 lines 11-15, Holly teaches that the compositions are for the treatment of ocular disorders and tear film abnormalities. Holly

goes on to state on col. 1, lines 35-40, "It has been recognized only in the last decade that many of the eye complaints related to persistent irritation, burning sensation, conjuctival vasodialation, ***inflammatory reaction***, occasional excessive tearing and photophobia are usually ***caused by a dry eye state***" (emphasis added). Suzuki's compositions containing drugs are for the treatment of inflammation. It would have been obvious to one of ordinary skill in the art therefore, to use the teachings together to form a tear film as well as treat the inflammation. Therefore, it would have been obvious to modify Suzuki.

Appellant argues that in the January 22, 2008 office action, the Examiner contends that the argument is not persuasive because the instant claims are composition claims and motivation to use the combination need not be the same as Appellant's motivation and that Appellant notes that no legal authority has been provided for this assertion. In response, the Examiner points out that the fact that Appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Appellant argues that the composition does more than yield predictable results and point out to page 4, lines 16-18 which apparently describe that an artificial tear formulation having polyvinyl alcohol, a polyvinyl acetate, a hydrophilic polymer and a phospholipid replicates all three layers of the normal human tear film. This argument is not persuasive since Holly's compositions for the treatment of dry-eye syndrome

contains all three polymers. Instant specification provides no comparative data with polymer combination with and without phospholipids.

Appellant argues that claim 2 recites that the phospholipid is formulated in polysorbate-80, glycerin, ethanol and water and that the combination of Suzuki, Guy and Holly fails to suggest using a phospholipid formulated in polysorbate-80, glycerin, ethanol and water. Appellant further argues that Suzuki discloses using solvents such as ethanol for preparing the emulsion, but the solvent is subsequently distilled off. In response, the Examiner points out that Suzuki's formulations still contain the lower alcohol such as glycerol and Appellant has not shown any criticality of the presence of ethanol. Instant claims do not even recite any specific amounts of ethanol and it is unclear from the reference whether the ethanol is completely removed. Furthermore, the Examiner respectfully directs the Board's attention to the fact that Appellant uses a commercially available mixture of phospholipid formulated in polysorbate-80, glycerin, ethanol and water and Appellant has not established that the ethanol in the compositions is critical. It is well-known in the art that ethanol is a solvent for phospholipids as also evident from Suzuki.

Appellant argues that claim 4 recites that the composition of claim 1 further includes water, one or more electrolytes to contribute to the well being of the corneal epithelium, one or more preservatives and one or more buffers and that there is no teaching or suggestion in the prior art of record of using one or more electrolytes that contribute to the well being of the corneal epithelium. In response, the Examiner points out to Example 2 of Holly which teaches the electrolytes such as calcium and

magnesium salts, buffers and preservatives. Guy also teaches preservatives and buffers (col. 5 and examples 1-37).

Appellant argues that claim 6 recites that the concentration of polyvinyl alcohol from about 0.5 % to 10 % by weight in water, the polyvinyl alcohol being about 96-99 % hydrolyzed, that the concentration of the polyvinyl acetate is from 0.5 % to 10 % by weight in water, the polyvinyl acetate being about 73 % to 93% hydrolyzed and polyvinyl pyrrolidone is from about 0.5 % to 10 % by weight in water and that the concentration of the phospholipid is from about 0.003 % to 0.02 % by weight in water and the prior art clearly fails to teach or suggest these claimed concentration levels. In response, the Examiner points out to Examples 1-3 where Holly tests polymers obtained from various manufacturers and tests the claimed amounts. With regard to the phospholipid amounts, the teachings of Suzuki on col. 3, lines 15-20 shows that these amounts can be varied depending upon the amount of the active agent.

Rejection 3:

Appellant's arguments have been fully considered, but are not persuasive. The Examiner has already addressed the arguments regarding Suzuki, Guy and Holly. Appellant argues that just because that the combination is readily available in the market under the trade name Amisol™, does not mean that it would have been obvious to use that product in that claimed combination. This argument is not persuasive. The prior art is suggestive of the use of these components in eye formulations and therefore, one of ordinary skill in the art would either combine these individually or use a readily

available product and avoid the step of mixing the individual components. The Examiner has already addressed Appellant's arguments regarding each claim.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the Examiner in the Related Appeals and Interferences section of this Examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Gollamudi S Kishore /

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/Frederick Krass/

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